

REMARKS

Claims 7, 8, 10-12, 28-35, 37-40, 43, 44, 46, 47 and 54-59 are pending in the application with entry of this Amendment. Claims 7, 28 and 43 are amended. New claims 57-59 are added. The amendments and new claims do not present new matter. *See, e.g.*, Figs. 29-31 (illustrating suction device 618 having outer or peripheral sealing surface carrying stimulation electrodes 604, and width of suction device across peripheral sealing surface is wider than tube and is the widest portion of the suction device. Applicant notes that there is no requirement that a claim amendment must include exactly the same nomenclature as provided in the specification. MPEP §608.01. Claims 12 and 29 were withdrawn from consideration. It is respectfully requested that these claims be reinstated upon allowance of respective independent claims from which they depend. Reconsideration and allowance of the application, as amended, are respectfully requested.

I. Office Action Remarks Regarding Prior Informal Objection and Rejection

As an initial matter, it is stated in the Final Office Action that the Examiner cannot determine why remarks concerning objections to claim language were included in the prior response, but that this was a moot issue. Applicants respectfully disagree and note that the remarks were submitted in response to remarks by the Examiner in the previous Office Action stating “Regarding the recitation ‘the suction device being removably securable to myocardial tissue’ in independent claims 7, 28 and 43, the examiner has objected to it above and has interpreted it as intended use and/or functional language in order to provide an examination” despite the absence of a formal objection to any claim. May 18, 2007 Office Action (p. 6) (emphasis added). Instead, the prior Office Action included only rejections under §103(a).

Since there is no formal objection to any claim, it is Applicant’s understanding that the Examiner’s remarks relate to a personal preference as opposed to a formal objection and, therefore, this matter warrants no further remarks. Moreover, if the Examiner is aware of legal precedent that states that limitations directed to structural properties including material properties (flexible), shape and size of a suction device amount to “functional” language or “intended use”, Applicant respectfully requests the Examiner to identify such precedent and explain how it applies to the pending claims.

Applicant also notes that allegations that certain structural features are “inherent” are different and involve different criteria and analysis than allegations that claim language is functional, but the Final Office Action appears to imply that they are the same and related. Final Office Action (p. 6). Thus, the basis of the apparent informal objection is not clear.

Moreover, the Final Office Action alleges that in certain instances, Applicant argues references individually rather than in combination. To the contrary, Applicant notes deficiencies of various references to show how the references, individually and in combination, fail to disclose, teach or suggest each limitation of a claim, which is the first requirement in any rejection under §103(a). Applicant provides additional remarks explaining why certain references would not be combined in view of the common knowledge and common sense of a person of ordinary skill in the art, *e.g.*, given the substantially different structural configurations of devices described by various references, and why certain references teach away from claim limitations. Thus, Applicant demonstrates why the cited references are deficient individually and in combination, and that all of the elements of various claims would not be disclosed even assuming that certain references would somehow be properly combined by a person of ordinary skill in the art.

II. Claims 7, 8, 10, 11, 28, 30, 40, 43, 44, 46 and 47 Are Patentable Over Lundback and Samson

Independent claims 7, 28 and 43 and respective dependent claims 8, 10, 11, 30, 40, 44, 46 and 47 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over U.S. Patent No. 4,736,749 to Lundback in view of U.S. Patent No. 6,185,442 to Samson (“Samson”). Applicants respectfully submit that the rejection is moot in view of claims 7, 28 and 43 as amended.

Lundmark fails to disclose, teach or suggest “a suction device formed from a flexible material” as recited in claims 7, 28 and 43. It is alleged in the Office action that the “suction device” is formed by the collection of elements 1-3 described by Lundback. Final Office Action (p. 2). As described by Lundback, element 1 is “arrangement 1” (Lundback col. 3, line 13), element 2 is an “intermediate element 2” (Lundback, col. 3, line 18) and element 3 is “backpiece 3” (Lundback, col. 3, line 16).

As further explained by Lundback, backpiece 3 is rigid and advantageously made of plastic. Lundback (Abstract; col. 2, line 5; col. 3, lines 23-24; col. 5, lines 28-29) (emphasis added). Similarly, intermediate element 2 has “a relatively rigid ring portion 9 with a circumferential sealing lip 13...” Lundback (col. 3, line 46) (emphasis added). A flange 17 on the intermediate element 2 elastically abuts against a lip 16 of the rigid backpiece 3, but the intermediate element 2 is made from silicon rubber or a similar material so that the intermediate element “has a relatively rigid ring.” Lundback (col. 3, lines 45-46) (emphasis added). Thus, the Office Action allegation squarely contradicts Lundback, which describes the intermediate component 2 as rigid, even if one part of that rigid component may elastically abut another component. Moreover, the ring 9 of the intermediate element is a “relatively rigid ring.” Lundback (col. 4, line 3) (emphasis added). It is also conceded in the Final Office Action that “Indeed sealing lip 13 is disclosed as being rigid.” Final Office Action (p. 7) (emphasis added).

Since the rejection relies on the collection of elements 1-3 as forming a “suction device”, as opposed to an individual element thereof, it naturally follows that it must be the collection of components that is formed of a flexible material, since claims 7, 28 and 43 recite *inter alia* “a suction device formed from a flexible material.” However, since so many elements of the alleged collection of elements 1-3, or components thereof, are rigid, it logically follows that the collection of element 1-3 cannot be “formed of a flexible material.”

Allegations that the collection of elements 1-3 is formed of a flexible material either 1.) improperly ignore the language of the claims, which recite the “suction device” is “formed” of a flexible material, 2.) improperly ignore the basis of the rejection that it is the collection of elements 1-3 that allegedly form a “suction device” as recited in the claims, and/or 3.) ignore the fact that multiple components are specifically described by Lundback as being rigid. Thus, the Final Office Action cannot, on the one hand, rely on a collection of components to support the rejection, then on the other hand, simply ignore certain “rigid” components and instead rely on an individual component that may not be rigid to allege that the collection of components is formed of a flexible material. Not only does this argument defy logic, but it is clearly inconsistent with the understanding of a person of ordinary skill in the art who would readily appreciate that a collection of elements 1-3 and the description of “rigid” components do not result in the collection being formed of a flexible material, even if one part may be elastic. The

Final Office Action, understandably, has provided no explanation as to how these fatal inconsistencies may be reconciled.

Accordingly, Applicant respectfully submits that Lundback fails to disclose, teach or suggest a suction device formed from a flexible material as recited in claims 7, 28 and 43. Moreover, given Lundback's description of various rigid components, the cited reference teaches away from a suction device formed from a flexible material, particularly considering that Lundback explains that the rigid backpiece is advantageously made of plastic. Lundmark (col. 3, line 24).

Lundback also fails to disclose, teach or suggest a suction device formed from a flexible material, "the suction device being connected to and coaxial with the distal end of the tube [which defines a central axis]" as recited in claims 7, 28 and 43. Rather, as conceded in the Final Office Action, "Lundback fails to disclose a distal surface that has normal vector (a direction away from the surface) that is aligned with the central longitudinal axis of the tube. In other words, the central axis of the tube and the central axis of the suction device (the axis that passes through the centers of 1, 2 and 3 and defines the direction of motion by which 1, 2, and 3 movably engaged) are not coaxial." Final Office Action (p. 7). Thus, Lundback discloses a configuration that is the opposite of the configuration recited in claims 7, 28 and 43, since Lundback describes a configuration in which a tube 8 defines an axis (along an "x" direction with respect to Fig. 1 of Lundback), whereas other elements are arranged at 90 degrees relative to this axis (*i.e.*, in the "y" direction). Thus, not only is Lundback clearly deficient relative to these claim limitations, but the cited reference also teaches away from claims 7, 28 and 43.

The Final Office Action also alleges that Applicant is reciting "some undefined axis" of the tube and another "undefined axis" of the suction device. The claims, as amended refer to a central axis for reference. Moreover, the basis of the Final Office Action remark is not clear since a tube defines a central axis and, therefore, Applicant is not reciting "some undefined axis" and the Final Office Action allegation is contrary to the known geometric structure of a tube.

Moreover, it is alleged that this issue "is moot" on the sole, general basis that the Examiner has cited a secondary reference (presumably Samson) that teaches providing a suction cup and tubing that are clearly coaxial with each other. Applicant respectfully disagrees in view of the substantially different structural configurations described by the cited references, and that Lundback teaches away from Applicant's claims. Further, the Final Office Action provides no

further explanation how, or a reason why, the structure described by Lundback would be substantially modified in this manner given the particular “90 degree” or transverse configuration of elements 1-3 relative to tube 8, which is the opposite of the configuration recited in claims 7, 28 and 43, and the opposite of the configuration described by Samson. Such substantial modifications would essentially transform the device described by Lundback into something that has a very different structural configuration that may render it inoperable for its intended purpose. Further, such modifications would appear to substantially increase the profile of the device described by Lundback, and in this regard, Lundback teaches away from any such configuration and substantial modifications.

Lundback also fails to disclose, teach or suggest a suction device formed from a flexible material, the suction device being connected to and coaxial with the distal end of the tube and having “a flexible distal portion that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue, the suction device extending from the tube distal end such that the peripheral sealing surface is located distally of the tube distal end and extends outwardly beyond an outer surface of the tube distal end such that suction device across the peripheral sealing surface is wider than the tube distal end” as recited in claims 7, 28 and 43. As discussed above, it is alleged in the Final Office Action that the collection of the arrangement 1, the intermediate element 2, and rigid backpiece 3 form a “suction device.” Final Office Action (p. 2). The Final Office Action also relies on the surface 4 described by Lundback and further alleges that the tissue contacting side 30 is a tissue stimulation electrode. The Office Action allegations are fatally deficient for a number of reasons.

Claims 7, 28 and 43 recite inter alia “a flexible peripheral sealing surface” having a shape and a size for being removably securable to myocardial tissue. As clearly shown in Figs. 2 and 3 of Lundback, the surface 4 and operative part 30 are not on an outer portion or periphery of a suction device. In contrast, Lundback explains that a stem 5 of the arrangement 1 including the surface 4 and part 30 is fastened into a corresponding female part 6 of the backpiece 3 in the middle of the backpiece 3 and through a hole 18 formed through the middle of the intermediate element 2. Accordingly, Lundback, once again, describes a structural configuration that is the opposite of the configuration recited in Applicant’s claims. Moreover, to the extent that the sealing lip 13 could somehow be considered to be a periphery of the device described by Lundback, despite the fact that the lip 13 is not an outermost portion, the cited reference explains

that “Part 2 [intermediate element 2], which is made from silicone rubber or a similar material, has a relatively rigid ring portion 9 with a circumferential sealing lip 13.” Thus, based on this description, the sealing lip 13 is rigid and not flexible (as also conceded in page 7 of the Final Office Action), consistent with Figs. 2 and 3 showing the lip 13 in its original, undeformed shape when the sealing lip 13 is pressed against tissue, which is a result of the lip 13 being rigid. Therefore, the rigid lip 13 cannot be peripheral sealing surface of a suction device formed of a “flexible” material.

Lundback also fails to disclose, teach or suggest such a suction device having a flexible peripheral sealing surface, and the “suction device extending from the tube distal end such that the peripheral sealing surface is located distally of the tube distal end and extends outwardly beyond an outer surface of the tube distal end such that suction device across the peripheral sealing surface is wider than the tube distal end” as recited in claims 7, 28 and 43. In contrast, it is alleged that the arrangement 1, intermediate element 2, and backpiece 3 collectively form a suction device, and further alleged that the surface 4 is a surface of the suction device. Final Office Action (p. 2). However, as shown in Figs. 2 and 3 of Lundback, for example, the right portion of the surface 4 extends past (*i.e.*, to the right) of the left or distal end of the tube 8, which extends through a side wall of the rigid backpiece 3.

Moreover, Lundback fails to disclose, teach or suggest such a suction device having a “flexible peripheral sealing surface” and “a tissue stimulation element that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction device” as recited in claims 7 and 28 and “tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface, for stimulating myocardial tissue without forming a transmural lesion in the myocardial tissue” as recited in claim 43. It is alleged in the Final Office Action that the “suction device” as recited in the claims is the collection of the arrangement 1, the intermediate element 2, and the backpiece 3, and further alleged that operative part 30 is a “tissue stimulation element.” Final Office Action (p. 2). However, as clearly shown in the Figures of Lundback, the part 30 is a part of the arrangement 1 that includes the surface 4 and the stem 5 that extends from the middle of the arrangement 1 and is inserted within a corresponding female part 6 of the backpiece 3 through hole 18 formed through the middle of the intermediate element 2.

Consequently, Lundback clearly fails to disclose, teach or suggest a tissue stimulation element supported “on the peripheral sealing surface of the distal portion of the suction device” as recited in claims 7 and 28 and tissue stimulation means “carried by the peripheral sealing surface of the distal portion of the suction device distal surface” since the cited operative element 30 is in a middle portion of the device. Moreover, to the extent that the sealing lip 13 can somehow be considered to be a periphery of the device described by Lundback, despite the fact that the lip 13 is not an outer or peripheral portion, the cited reference explains the lip 13 is part of a rigid ring portion (as opposed to being flexible), and it is clear that Lundback does not disclose, teach or suggest the lip 13 carrying the operative part 30, particularly considering that the operative part 30 is much larger than the pointed bottom surface of the sealing lip 13. Lundback (Fig. 1).

Additionally, Lundback is related to a diagnostic or therapeutic arrangement for attachment to a skin surface (*i.e.*, an outer surface of a body) as opposed to having a suction device that includes a flexible peripheral sealing surface having a shape and a size for being removably securable to myocardial tissue, *i.e.*, inside of the body.

Lundback also fails to disclose, teach or suggest the limitation, “wherein the suction device is substantially cup-shaped” recited in claims 10 and 46. It alleged that only one component of this collection of components, *i.e.*, intermediate element 2, is “substantially cup shaped.” However, as discussed above, the rejection is based on the collection of elements 1-3 as the suction device, not a single element of that collection. Inconsistent allegations cannot support the rejection.

In an attempt to fill these determinative deficiencies of Lundback, the Office Action relies on Samson as allegedly disclosing a suction device, tube and electrode, and that a distal surface of the suction device has a normal vector that is aligned with the central axis of the tube. Final Office Action (p. 3). Samson, however, does not cure the substantial deficiencies of Lundback and has its own deficiencies. Thus, the rejection under §103(a) cannot stand.

For example, Samson fails to disclose, teach or suggest the combination of “a suction device” formed from a flexible material and having a “flexible distal portion that includes a flexible peripheral sealing surface” as recited in claims 7, 28 and 43, and “a tissue stimulation element that is too small to form a transmural lesion in myocardial tissue, the tissue stimulation element being supported on the peripheral sealing surface of the distal portion of the suction

device” as recited in claims 7 and 28 and “tissue stimulation means, carried by the peripheral sealing surface of the distal portion of the suction device distal surface, for stimulating myocardial tissue without forming a transmural lesion in the myocardial tissue” as recited in claim 48.

In contrast, Samson describes an electrode 16 that is “mounted within the suction cup [10].” Samson (col. 3, line 47; Fig. 2) (emphasis added). In other words, as clearly illustrated in Fig. 1 of Samson, the electrode 16 is located in the middle of the suction cup 10, *i.e.*, not on a peripheral rim 13 of the suction cup 10. Samson explains that the reason for this particular configuration is to enable a user to manipulate a bellows 14 so that the middle electrode 16 may be drawn down into contact with the scalp of a fetus. Samson (col. 3, lines 44-46, 57-61; Fig. 2 (illustrating user pushing bellows with thumb and to move electrode 16).

Samson also fails to disclose, teach or suggest “a tissue stimulation element that is too small to form a transmural lesion in myocardial tissue” as recited in claims 7, 28 and 43. In stark contrast, Samson describes a probe having a suction cup 10 “intended for attachment to the head 11 of a fetus for the purpose of monitoring characteristics of the fetus.” Moreover, based on the Figures in Samson, the configuration recited in claims 7, 28 and 43 is not possible since diameter of the electrode 16 shown by Samson is significantly larger than the width of the rim 13, and therefore, the rim 13 is not suitable for supporting the large electrode. Noteworthy is that the remarks beginning on page 8 of the Final Office Action have not addressed this significant difference.

Consequently, Samson does not cure the multitude of significant deficiencies of Lundback and has its own deficiencies. Lundback and Samson, therefore, individually and in combination, fail to disclose, teach or suggest each limitation of claims 7, 28 and 43, which is a requirement of any rejection under 35 U.S.C. §103(a). Applicant respectfully submits that independent claims 7, 28 and 43 are patentable over Lundback and Samson. Dependent claims 8, 10, 11, 30, 40, 44, 46 and 47 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed allowable. MPEP §2143.03. Thus, Applicant respectfully requests that the rejection of these claims under §103(a) be withdrawn.

Further, although Applicant submits that the amendments and above remarks dispose of the rejection, Applicant also notes that the modifications involved in the alleged combination of

Lundback and Samson would substantially alter the configuration and use of the device described by Samson and/or render the device described by Samson inoperable for its intended purpose. Moreover, Samson teaches away from Applicant's claims given the reasons for the electrode 16 being within the middle of the suction cup 10 as opposed to on a distal, peripheral surface as recited in claims 7, 28 and 43.

II. Claims 31-33 and 37-39 Are Patentable Over Lundback, Samson and Rau

Dependent claims 31-33 and 37-39 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view Samson and further in view of U.S. Patent No. 4,685,466 to Rau ("Rau"). Dependent claims 31-33 and 37-39 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed allowable. MPEP §2143.03.

It is conceded in the Office Action that Lundback and Samson fail to disclose certain stimulation electrode dimensions as recited in the claims. Rau is cited for this limited purpose. Rau, however, does not disclose, teach or suggest all of the above-discussed claim limitations missing in Lundback and Samson and has its own limitations.

The Office Action cites col. 3, lines 1-15, col. 4, lines 29-49 and Figures 4-6 of Rau to support the rejection. It is stated in the Office Action that "Rau provides all of the recited dimensions" of the claimed invention based on Rau disclosing a needle. Office Action. (p. 4). However, the cited sections of Rau do not recite any specific dimensions for the needle, and there is no evidence set forth in the Office Action to establish that the needle described by Rau necessarily has the dimensions as recited in claims 31-33 and 37-39. The Final Office Action refers to a new section of Rau (col. 3, lines 53-68) as allegedly disclosing these claim limitations and also refers to Figures 1a-7.

Figures 1a-7 of Rau, however, are understandably silent as to such dimensions. Further, col. 3, lines 53-68 explain that three or four points are separated from each other by 0.5mm, but do not otherwise specify stimulation element dimensions. Further, while Rau explains that points are arranged at a distance of approximately 0.5mm from one another, claim 31 recites a stimulation element defining a perimeter of "about 1.5mm to 3mm", which is 300-600% larger than the "spacing" dimension provided in col. 3, line 66. Further, although Applicant submits that the amendments and above remarks dispose of the rejection, given the relative dimensions of

components provided in the Figures of Rau, the Office Action has not explained how a needle, which is longer than its width, would have a thickness of about 0.01mm as recited in claims 32 and 38. Therefore, the Office Action allegations regarding Rau cannot support the rejection, and Applicant respectfully requests that the rejection of these claims under §103(a) be withdrawn.

Moreover, Applicant respectfully submits that a person of ordinary skill in the art would not combine the cited references. It is alleged in the Office Action that it would have been obvious to combine Lundback and Rau and modify Lundback to provide a suction electrode with a needle electrode in order to provide fixation without electrode paste or jelly to reduce skin resistance. Office Action (p. 5). However, Lundback does not even refer to “paste” or “jelly.” Accordingly, the basis for the reason for combining the references is not clear, particularly considering that Lundback describes use of vacuum and is not related to reducing skin resistance. If the rejection stands, Applicant again respectfully requests the Examiner to identify the section of Lundback that describes use of paste or jelly and the reason for use of a needle electrode in Lundback since the Final Office Action fails to do so, and the alleged combination is not consistent with the common knowledge of persons skilled in the art and lack common sense given the substantially different structural configurations and required modifications to Lundback.

Applicants also respectfully submit that a person of ordinary skill in the art would not combine the cited references given the particular and different structural configurations and functionality. It is alleged in the Office Action that the electrode provides a needle configuration “to provide fixation.” Office Action (p. 4). More specifically, Rau explains that the needle point penetrates into cell layers of the skin to provide “an exceptionally effective fastening of the electrode” to the skin. Rau (col. 3, lines 46-49). However, Lundback explains “the holder is held firmly by suction” against the skin when the vacuum valve is re-opened. Lundback (Abstract) (emphasis added), and Samson explains that vacuum is used to cause a suction cup 10 to deform and be “secured to the fetal head.” Samson (col. 3, lines 59-61). Thus, a needle point as described by Rau is not required in the devices described by Lundback and Samson since devices are already held firmly against or secured to skin.

Further, Rau explains that use of the needle point to penetrate cell layers of the skin results in “indention points” that are formed in the skin. Samson, however, describes securing a suction cup having an electrode by vacuum to a head of a fetus in a “non-invasive” manner using

vacuum and a suction cup. Samson (Abstract). Applicant respectfully submits that a person of ordinary skill in the art would not combine Samson and Rau since it would not be desirable to use a needle point to penetrate the skin of a fetal head and form indentation points (even if temporary) in a fetal head when Samson achieves its objectives in a non-invasive manner by use of suction.

Further, it is alleged that such modifications for purposes that are not described by Lundback would be used “to reduce skin resistance.” In this regard, Rau is referring to electrical resistance of the skin to obtain more accurate measurement results with reduced interfering signals (movement artifacts, noise, etc.). Lundback, however, does not even discuss electrical resistance of the skin, and since Lundback describes a relatively flat surface 4, it would appear that the “needle” and “skin resistance” considerations of Rau are not issues in the device described by Lundback.

III. Claims 34 and 35 Are Patentable Over Lundback, Samson and Colliou

Dependent claims 34 and 35 stand rejected under 35 U.S.C. §103(a) as allegedly being unpatentable over Lundback in view of Samson and further in view of U.S. Patent No. 7,020,531 to Colliou (“Colliou”). Dependent claims 34 and 35 incorporate the elements and limitations of independent claim 28 and, therefore, are also believed patentable. MPEP §2143.03.

It is conceded that Lundback fails to disclose that the source of stimulation is configured to provide stimulation pulses that are about 1 msec in duration, 10mA and two stimulation pulses per second, and cites Colliou for this limited purpose. Colliou, however, does not provide the above-discussed claim limitations missing in Lundback and Samson. Therefore, the cited references, individually and in combination, fail to disclose, teach or suggest each element of claims 28, 34 and 35. MPEP §2143.03. Accordingly, dependent claims 34 and 35, which incorporate the elements and limitations of independent claim 28, are believed allowable over the cited references.

Further, Applicant respectfully submits that a person of ordinary skill in the art would not combine the cited references since they describe devices having different structural configurations for different purposes. Lundback is directed to a suction / vacuum device for attachment to skin (Lundback, col. 2, line 1), Samson is directed to a suction device that is

secured to a fetal head (Samson, col. 3, line 37), and Colliou is directed to a device that is attached to a stomach wall (Colliou, Abstract).

IV. New Claims 57-59 Are Patentable Over the Cited References

Dependent claims 57-59 incorporate the elements and limitations of respective independent claims 7, 28 and 43 and, therefore, are also believed patentable in view of the above remarks. MPEP §2143.03.

Further, Lundback and Samson are clearly deficient relative to these claims, which recite inter alia “wherein the peripheral sealing surface is the widest portion of the suction device.” In contrast, Lundback describes a surface 4 and operative part 30 in the middle of arrangement 1, and Samson describes an electrode 16 that is also in the middle of a suction cup 10.

CONCLUSION

Applicant respectfully requests entry of this Amendment and allowance of the application in view of the forgoing remarks. If there are any remaining issues that can be resolved by telephone, Applicant invite the Examiner to kindly contact the undersigned at the number indicated below.

Respectfully submitted,

VISTA IP LAW GROUP LLP

Dated: February 11, 2008

By: / Gary D. Lueck /

Gary D. Lueck
Reg. No. 50,791
Attorneys for Applicants

12930 Saratoga Avenue, Suite D-2
Saratoga, California 95070
Telephone: (408) 777-2905
Facsimile: (408) 877-1662